REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected. Claim 1 has been amended. Support for the amendment is provided in the specification at pages 27 through 31. No new matter is added by this amendment. Reconsideration is respectfully requested in light of this amendment and the following remarks.

I. Objection to Claim 1

The objection to claim 1 as encompassing non-elected inventions has been maintained. Claim 1 has also been objected to as the Examiner suggests that it is not clear which "levels" are referred to.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to be drawn to the elected subject matter and to clarify that the level of SEQ ID NO:7 or 8 is detected.

Withdrawal of this objection to claim 1 is respectfully requested in light of these amendments.

II. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph - Written Description

The rejection of claim 1 under 35 U.S.C. § 112, first paragraph, pertaining to lack of written description for a method for detecting prostate cancer, comprising determining a change in the "levels" of a polynucleotide comprising SEQ ID NO: 7 or 8 has been maintained. Specifically, the Examiner suggests that Applicants have not disclosed the structure of a gene containing a polynucleotide sequence comprising SEQ ID NO:7 or 8, which is a requirement for written description, as taught by the court.

Applicants respectfully traverse this rejection as the case law to which the Examiner refers was related to a composition claim, not a method claim as in the instant application. Further, the composition claim was not limited to particular sequences as in the instant method claims. Accordingly, the Examiner basis for this rejection is flawed.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to state that a level of SEQ ID NO: 7 or 8 is determined. The nucleic acid sequences of SEQ ID NO: 7 and 8 are both taught in the instant application. Accordingly, definitive structural features of the claimed sequences are provided in the specification so that one of skill in

the art can predictably identify the encompassed molecules as being identical to those now claimed. Further, teaching of these sequences in the sequence listing and data evidencing their detection in prostate cancer tissue establishes Applicants' possession of the claimed invention. Thus, the written description requirements of 35 U.S.C. § 112, first paragraph, as set forth in MPEP § 2163.02 are clearly met for the pending claim.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

III. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, -Lack of Enablement

The rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has also been maintained.

Specifically, the Examiner suggests that the claims still read on a method for detecting "gene levels" of a polynucleotide and that it is unpredictable that there is any change in the gene levels in prostate cancer.

As discussed in Section II, *supra*, claim has been amended to be drawn to detecting a level of SEQ ID NO:7 or 8. MPEP § 2164.01(b) is quite clear; as long as the specification discloses at least one method of making and using the claimed invention that

bears a reasonable correlation to the entire scope of the claims, then the enablement requirement of 35 U.S.C. § 112 is satisfied. Detecting levels of SEQ ID NO:7 or 8 prostate cells or tissues is taught in the instant specification at pages 27 through 31. Further, it is well established that prostate cells are found in other bodily fluids such as blood. Accordingly, the instant specification is enabling for the instant claims drawn to a method for diagnosing the presence of prostate cancer in a patient which comprises determining a level of SEQ ID NO: 7 or 8 in prostate cells or tissues or bodily fluids containing prostate cells in the patient and comparing that level to the level of SEQ ID NO: 7 or 8 in prostate cells or tissues or bodily fluids containing prostate cells from a normal human control.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is therefore respectfully requested.

The Examiner further suggests that claim 1 lacks enablement under 35 U.S.C. § 112, first paragraph, for determining a change in the level of a polynucleotide comprising SEQ ID NO:7 or 8 in "any cell or tissue". Specifically, the Examiner suggests that the claims read on detecting metastatic cancer and that it is unpredictable that metastatic cancer will still express SEQ ID NO:

7 or 8. Further, the Examiner suggests that even if the claims were limited to a method for detecting primary or localized prostate cancer, there is no correlation between expression in prostate cancer tissue and expression in any other tissue or cell.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that an increase in the level of SEQ ID NO:7 or 8 is associated with cancer. Further, as discussed in the preceding paragraph, claim 1 has been amended to state that the levels are determined in prostate cells or tissues, in accordance with teachings at page 27 through 31 of the instant specification or bodily fluids containing prostate cells, in accordance with the well known fact that prostate cells can be found in other bodily fluids such as blood. The claim, as amended is thus clearly enabled by the instant specification.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is therefore respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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